K081678

510(k) Summary

5 510(k) Summary

Submitted by: KLS Martin GmbH + Co. KG
Am Gansacker 1b
79224 Umkirch
Germany

JUL 29 2008

Contact Person: Dr. Bernhard Hug

Date Prepared: April 23 2008

Common Name: Electrosurgical Generator (ESU) System and Argon Beamer System

Trade/Proprietary Name:
Conmed Beamer System CE600

Classification Name:
Electrosurgical cutting and coagulation device and accessories
(21 CFR 878.4400)

Product Code: 79GEI

Legally Marketed Predicate Devices:
Erbe VIO 300D (K023886 & K060484) and
Erbe VIO APC2 (K024047) and
Erbe APC 300 (K963189) and
Erbe APC Connector Hose (K013348) and
Erbe ICC 200 (K933157) and
Sutter Electrosurgical Cables (K073450)

Device Description

The Conmed Beamer System CE600 with Accessories is an electrosurgical system that uses high frequency (HF) electrical current waveforms to cut and/or coagulate tissue whereby coagulation can be assisted by Argon gas.The system comprises of the following components:

Electrosurgical unit (ESU) Beamer Mate CE200

The Beamer Mate CE200 is an electrosurgery generator for monopolar and bipolar application. It features two monopolar and two bipolar outputs that can be set to output power, current mode and activation source independently. For each output, these settings can be provided for cutting mode and coagulation mode in separate arrays, called channels, on a color TFT display. This TFT display provides the user with actual settings and operational information of all four outputs and enables operation of the device by navigation in menus on the display using channel selection buttons, a MENU button and a rotary switch with axial pushbutton function. The device is intended as a program-based HF device.The manufacturer delivers the unit with exemplary programs for a whole range

of different applications. However, the surgeon is free to modify these programs and store them under a new name in accordance with his/her own preferences and individual requirements. The unit has various cutting and coagulation current forms with defined grades or flexible wattage ranges to provide flexibility in interventional applications. Further features are monitoring of the return electrode, activation of HF output power by finger switches or by footswitch and service functions, accessible by Setup menu. Also, the unit can be used in association with an Argon Unit, the Beamer Plus CB200. The ESU is supplied nonsterile and is reusable.

Argon gas supply unit Beamer Plus CB200

The Beamer Plus CB200 enables and controls the gas flow required for the surgical process of argon beam coagulation. Terminals include argon gas inlet from the gas cylinder's pressure reducer, gas outlet for connection to the argon probe and a socket for connection with the Beamer Mate CE200 by means of CE/CB interface cable CB200-A03. Power supply and control is performed by the ESU, setting of flow rates and other beamer parameters as well as gas flow activation is done by the ESU. The only operation element at the CB200 is a "Purge" key that starts a three second's gas flow for filling a freshly connected probe with argon gas. The housings of CE200 and CB200 are matched for stacking both units with the CE200 upside. The housings are equipped with means to prevent horizontal movement of the units which enables placing on inclined surfaces without the hazard of slipping off or being torn off by connected cables or accessories. The CB200 is supplied nonsterile and is reusable.

Pressure reducer

The pressure reducer (CB200-A02) is an essential accessory delivered with the CB200 Beamer Unit. It drops the gas pressure of the argon gas cylinder which may be as high as 200 bar to a pre-regulated pressure in the range of about 4 bar which is input to the Argon Unit. The pressure reducer is equipped with a CGA580 connector at the high pressure side and a fast-lock connector at the beamer's side.

Cart CC200

The cart is intended as the system's carrier with a top plate to pick up the stacked ESU and Beamer Unit as well as the ESU alone. Inside the cart's body, an argon gas cylinder with pressure reducer can be placed and fixed. The cart is equipped with four swivel castors on stems protruding from the lower corners which provide mobility combined with high tilt stability. Two of four castors feature foot-tip operable brake levers to prevent random movement of the cart. A non-detachable (detachable just by the help of a tool) mains cord feeds the mains power through the cart to two cables with mains plug which allow mains supply of two units assembled at the cart, i.e. the ESU and a further unit that requires mains power. Further properties are three terminals for common ground connection, a basket for picking up accessories, a standard rail for infusion holders or else, a pickup for the foot switch and a handle for moving the cart.

Footswitches

A double footswitch (CE200-A01) is an essential accessory delivered with the ESU. It enables activation of cutting mode HF output power by pressing the yellow pedal or activation of coagulation mode HF output power by pressing the blue pedal. Allocation of the footswitch to one of the HF outputs is done in the main menu of the output channels. A single footswitch (CE200-A02) is optional delivered with the ESU.

K081678

510(k) Summary

Reusable Cable for Neutral Electrodes (CE200-A04)
The Reusable Cable for Neutral Electrodes (CE200-A04) connects disposable return electrodes (neutral electrode, patient plate) attached to the patient's skin to the ESU. This cable is intended for use with disposable neutral electrodes designed for cable clip connection. This cable belongs to the Applied Part of the system, is reusable and non sterile.

Connecting Cable for flexible argon probes
The Connecting Cable for flexible Argon Probes (CB200-A01) is an essential accessory in combination with the Argon Unit to connect argon assisted instruments with the ESU and with the Argon Unit which means that it features an electric conductor for HF power and a hose as guidance for the argon gas. The connecting cable is provided non sterile and is reusable. The cleaning and sterilization processes have been validated and are provided in the Instructions for Use to the user.

Intended use

The ConMed Beamer System CE600 with Accessories is intended to deliver electrosurgical current and Argon gas for the cutting, coagulation and argon beam assisted coagulation on tissue when used in conjunction with compatible applicators or probes.

Similarities and Differences of the Device to the Predicate Device

Electrosurgical unit (ESU) Beamer Mate CE200:

Similarities to Predicate Device
Both devices are intended for the same use. The handling of both devices is based on programs, both units use a color TFT display to show actual settings of the output channels and to manage the "background" settings in menus. Both units feature channel selection buttons to select a channel for being set. Both units use finger switches or foot switches for HF power activation. In both systems, the foot switch pedals can be allocated to any output. Both devices feature monopolar cutting currents with low, medium and higher hemostasis during cutting and feature special current modes for gastrointestinal procedures where cutting phases alternate with coagulation phases. Both devices feature monopolar coagulation current modes for soft coagulation, for preparation and for non-contact coagulation with high voltage what is a prerequisite to generate a consistent argon beam. The output characteristics (Power, Impedance Matching, Voltages and Frequencies) are equivalent and same effective. Both devices feature bipolar cutting and coagulation currents. Return electrode monitoring of single-plate and dual-plate electrodes is possible with both units.

Differences to Predicate Device
The CE200 features two fixed combo sockets M1 and M2 for monopolar current which accept the three-pin connector which is most common in the US market as well as the "Bovie-Plug", and two fixed sockets for bipolar current for connection of two-pin connectors with 28mm separation. The upper bipolar socket B1 is a combo socket which accepts a coaxial 12mm plug also. The lower bipolar socket B2 accepts the two-pin connector and

510(k) Summary

features two additional 2mm sockets for bipolar finger switch activation and bipolar instrument recognition. The Predicate Device uses three modular sockets in interchangeable drawers which may be monopolar, bipolar or both as well. Channel selection at the CE200 is done by pressing the yellow key of an output to set or change the cutting properties of this output or by pressing the blue key of this output to set or change its coagulation properties. During this procedure, the settings of all other channels are displayed simultaneously which gives an overall overview of the system's setting. Display of settings of a channel which is not used may be blanked by pressing the channel selection button and keeping it pressed for two seconds. With the Predicate Device, output selection is done by pressing the selection button at the output. The screen then displays the properties of this selected channel only, selection of a certain property is done by touch pads which are embedded in the frame of the display unit. With the CE200, changing of values and log-in is done by means of a rotary switch with axial push function while the Predicate Device uses three pushbuttons for the same purpose.

Argon gas supply unit Beamer Plus CB200:
Similarities to Predicate Device
Both devices generate a controlled argon gas flow which occurs on activation of an argon coagulation current at the ESU. Both beamer systems are designed to operate with their dedicated ESU only since power supply, flow activation and flow control is done by the ESU. Argon beamer system state is displayed on the ESU in both systems. Both systems feature a "Purge" key to remove residual air out of an argon probe and flush the probe with argon gas.
Differences to Predicate Device
ESU CE200 and Argon Unit CB200 are connected by means of a connection cable that supplies auxiliary power and control signals from the ESU to the Argon System. HF-power is not fed through the Argon Unit. With the Predicate Device, the connection between both system components is done by case-to case connectors which are incorporated into the bottom of the ESU and the top of the argon unit. This connection serves also as a HF power feedthrough from the ESU to the argon unit. With the system CE200 and CB200, the connection of the argon probe is done at one of the monopolar outputs M1 or M2 of the CE200 using the standard three-pin connector, and at the male luer-lock gas outlet of the CB200. With the predicate Device, electric and gas connection is done at the argon unit using a special multifunctional plug and a female luer-lock gas outlet.

Pressure reducer:
Similarities to Predicate Device
The pressure reducer CB200-A02 is the same model (same technology, same materials, same characteristics) from the same manufacturer (Linde company) as the Predicate Device.

Cart CC200:
Similarities to Predicate Device
Functionality of both carts is the same.
Differences to Predicate Device
The cart CC200 has a mains cord which is detachable only by use of a tool. The Predicate Device has a detachable mains cord and outlet sockets for mains power instead of cables so that additional connection cables are required unless the mains cord is connected to the ESU directly.

K081678

510(k) Summary

Connecting Cable for flexible argon probes
Similarities to Predicate Device
Both – the new and the predicate Connecting Cables have the same intended use, principles of operation and technological characteristics. They are non-sterile and reusable. The connector receptable for the flexible argon probes is compatible to the Conmed CET Argon Probes. The products have no patient contact.
The conecting cable has the same dimensions in length and diameter.
Differences to Predicate Device
The Gas Connector of both devices is Luer-Lock, whereas the Predicate is a male connector and the New Device has a female connector. Within the New Device the HF-Plug is a Standard 3 pin-plug, whereas the Predicate has a special designed plug. The minor differences do not affect the safety or effectiveness of the product.

Conclusion

The Conmed Beamer System with its component CE200 shows same performance of the current modes in comparison with the Predicate Device and thus represents good substantial equivalence to the Predicate Device.
The fact that the HF power is not fed through the CB200 Argon Unit as it is the case with the Predicate Device does not affect the clinical properties at all. Since all other technical details are the same, the CB200 with accessories represents also substantial equivalence to its predicate Device.
The CC200 cart shows same properties as its Predicate Device. Minor differences do not affect the clinical properties of the system.
Thus, the system CE600 with accessories raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 2008

KLS Martin GmbH + Co. KG
% TÜV SÜD America, Inc.
Mr. Norbert Stuiber
Third Party Reviewer
1775 Old Highway 8 Northwest
New Brighton, Minnesota 55112

Re: K081678
Trade/Device Name: ConMed Beamer System CE600
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 11, 2008
Received: July 14, 2008

Dear Mr. Stuiber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known): K081678

Device Name:
Conmed Beamer System CE600.

Indications For Use:

The ConMed Beamer System CE600 with Accessories is intended to deliver electrosurgical current and Argon gas for the cutting, coagulation and argon beam assisted coagulation on tissue when used in conjunction with compatible applicators or probes.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Melkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K081678